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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/671,461	09/27/2000	Arne Staby	5784.210-US	6001

23650 7590 05/31/2005

NOVO NORDISK, INC.
PATENT DEPARTMENT
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PRINCETON, NJ 08540

EXAMINER

KAM, CHIH MIN

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 05/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/671,461	Applicant(s) STABY, ARNE	
	Examiner Chih-Min Kam	Art Unit 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,4,6 and 11-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,4,6 and 11-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09/522,694.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/15/05</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. The Request for Continued Examination (RCE) filed March 15, 2005 under 37 CFR

1.114 is acknowledged. An action on the RCE follows.

Status of the Claims

2. Claims 2, 4, 6 and 11-25 are pending.

Applicants' amendment filed on March 15, 2005 is acknowledged. Applicants' response has been fully considered. Claims 2, 4, 6, 11-13 and 15 have been amended, and new claims 16-25 have been added. Thus, claims 2, 4, 6 and 11-25 are examined.

Rejection Withdrawn

Claim Rejections - 35 USC § 112

3. The previous rejection of claims 6, 11, 12 and 15 under 35 U.S.C. 112, second paragraph as being indefinite, is withdrawn in view of applicant's amendment to the claim, and applicants' response at page 6 of the amendment filed March 15, 2005.

Claim Rejections - 35 USC § 102

4. The previous rejection of claims 2, 6, 11, 13 and 14 under 35 U.S.C. 102(e) as being anticipated by Korc *et al.* (US 2003/0103980 A1, priority date October 16, 1998), is withdrawn in view of applicant's amendment to the claim, and applicants' response at page 7 of the amendment filed March 15, 2005.

Claim Rejections-Obviousness Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686

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F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 2, 4, 6 and 11-25 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3, 4, 8, 9 and 12-38 of co-pending application 10/176,410 (US 2003/0027996; based on the amendment filed March 17, 2005). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 2, 4, 6 and 11-25 in the instant application disclose a method for purifying a peptide or a specific peptide (e.g., glucagon-like peptide-1 or factor VII) from a mixture comprising the peptide and related impurities, the method comprising (a) eluting the related impurities of the mixture from anion exchange chromatography matrix using a solution comprising an organic modifier, water, optionally a salt component and optionally a buffer, at a linear or step gradient or isocratically in salt component and at a pH optionally maintained with a buffer, so that the impurities which have a lower negative net charge than the peptide can be removed; and optionally without an intervening step, (b) subsequently, eluting the peptide in the absence of an organic modifier by an aqueous solvent optionally with a salt component, at the same or lower pH optionally maintained with a buffer. This is obvious variation in view of claims 3, 4, 8, 9 and 12-38 of the co-pending application which disclose a method for purifying a glucagon-like peptide-1 (GLP-1) peptide or a factor VII from a mixture comprising the peptide and related impurities, the method comprising eluting the peptide and the related impurities of

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mixture from anion exchange chromatography matrix using a solution comprising an organic modifier, water, optionally a salt component and optionally a buffer, with a linear or step gradient or isocratically in salt component and/or with a linear or step pH gradient or at a constant pH, wherein the pH should be in the range so that the peptide has a negative net charge different from that of the related impurities so as to remove the related impurities. Both sets of claims cite a method for purifying a peptide or a specific peptide such as glucagon-like peptide-1 or factor VII from a mixture comprising the peptide and related impurities by eluting the impurities from the anion exchange chromatography with a solution comprising an organic modifier, water, optionally a salt component and optionally a buffer. Thus, claims 2, 4, 6 and 11-25 in present application and claims 3, 4, 8, 9 and 12-38 in the co-pending application are obvious variations of a method for purifying a peptide or a specific peptide from a mixture comprising the peptide and related impurities by eluting the impurities from the anion exchange chromatography with a solution comprising an organic modifier, water, optionally a salt component and optionally a buffer.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 2, 4, 6 and 11-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claims 2, 4, 6 and 11-25 are indefinite because of the use of the term “optionally a salt component” or “optionally a buffer”, it is not clear how a solution comprising an organic modifier, water, but without a salt component and without a buffer, can have a linear or step gradient or isocratically in salt component during the elution, and how a pH of the solution is maintained without a buffer. Claims 6, 11-20 and 22-25 are included in the rejection because they are dependent on rejected claims and do not correct the deficiency of the claim from which they depend. It appears that Examples 13-17 (pages 29-30 of the specification) indicate a solution comprising various percent of ethanol (e.g., 42.5%) and 0.15% w/w triethanolamine, pH 7.5 is used for elution, and the impurities are eluted from anion exchange column with a salt gradient of sodium citrate.

Conclusion

7. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4.30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.

Patent Examiner



**CHIH-MIN KAM
PATENT EXAMINER**

May 26, 2005